

CRITICAL CHARACTERISTICS

52.246-4550

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- a. The contractor's processes shall be designed to prevent the creation or occurrence of critical nonconformances. The contractor shall establish, document and maintain specific procedures, work and handling instructions and process controls relating to any critical characteristics.
- b. The contractor shall assure his critical processes are robust in design such that product and performance are relatively insensitive to design and manufacturing parameters. A robust design anticipates changes and problems. Robust processes shall be designed to yield less than one nonconformance in one million.
- c. An inspection/verification system shall be employed that will verify the robustness of your critical processes. Maximum use should be made of automated inspection equipment to accomplish verification of product quality. Mistake proofing techniques of your material handling and inspection systems are encouraged.
- d. Previous Practices/Special Characteristics. As a result of previous practices, the government's technical data may refer to "Critical" (not annotated with I or II) and "Special" characteristics. Characteristics classified as "Critical" (not annotated with a I or II) shall be subject to all requirements herein associated with Critical (I) characteristics and level I Critical nonconformances. Unless otherwise stated in Section C, characteristics classified as "Special" shall be subject to all requirements herein associated with Critical (II) and Level (II) Critical nonconformances.
- e. Contractor Identified Critical Characteristics List (CICCL). Not including critical characteristics defined in the government's technical data (drawings, specifications, etc.), the contractor shall identify and document all material, component, subassembly and assembly characteristics whose nonconformances may result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the product. All additional critical characteristics identified by the contractor shall comply with the critical characteristic requirements of the technical data package, supplemented herein. The contractor's additional critical characteristics shall be classified as "Critical (I)" or "Critical (II)", and shall be reviewed and approved by the procuring activity prior to manufacturing (DI-SAFT-80970A). The following definitions are provided.

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Level I critical nonconformance. A nonconformance of a critical characteristic that judgment and experience indicate would result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the product; or a nonconformance that judgment and experience indicate would prevent performance of the tactical function of a weapon system or major end item. The following (as a minimum) are classified as Level I critical nonconformances:

(1) A nonconformance that will result in a hazardous or unsafe condition (often referred to as a single point failure).

(2) A nonconformance that will remove or degrade a safety feature (such as those in a safe and arm device or fuzing system).

(3) A nonconformance that will result in violation of mandatory safety policies or standards.

Level II critical nonconformance: A nonconformance of a critical characteristic, other than Level I. This includes the nonconformance of a characteristic that judgment and experience indicate may, depending upon the degree of variance from the design requirement, the presence of other nonconformances or procedural errors, :

(1) result in a hazardous or unsafe conditions for individuals using, maintaining or depending upon the product, or

(2) prevent performance of the tactical function of a major end item.

f. In the event that a Critical nonconformance is found anywhere in the production process, the contractor, as part of his quality system, shall have procedures in place to ensure:

(1) The nonconformance is positively identified and segregated so that there is no possibility of the item inadvertently re-entering the production process. This control shall be accomplished without affecting or impairing subsequent defect analysis.

(2) The operation that produced the defective component or assembly and any other operations incorporating that component or assembly is immediately stopped.

(3) The government is immediately notified of the critical nonconformance (telephonically and electronic mail.) (DI-SAFT-80970A).

(4) Any suspect material (material in process that may contain the same defect) is identified, segregated and suspended from

any further processing.

(5) An investigation is conducted to determine the cause of the deficiency and required corrective actions. A report of this investigation shall be submitted to the government (DI-SAFT-80970A). The use of the DID report shall not delay notification to the government.

(6) A request to restart manufacturing or to use any suspect material associated with the critical nonconformance is submitted to the government (DI-SAFT-80970A). Restart of production shall not occur until the investigations are complete or upon authorization from the procuring contracting officer. All objective evidence of the investigations to date shall be available for review at the time of restart. Suspect materiel found to be nonconforming shall not be used without Government approval.

g. The contractor may develop alternative plans and provisions relative to government or contractor identified Critical level (II) characteristics. The provisions shall be submitted to the government for advanced approval and shall address the following:

(1) Complete explanation of potential failure mode(s) together with supporting historical and statistical data.

(2) Pre-established plan of action (POA) to be taken when a critical nonconformance occurs and a description of controls to ensure there is no possibility of the nonconforming item inadvertently entering the production process.

(3) Means of tracking nonconformance rate, investigative results and corrective actions taken.

(4) Method to immediately verify that a produced critical nonconformance is consistent with the identified failure mode(s) and does not exceed the historical nonconformance rate.

The contractor can resume production without specific government approval based upon the pre-approved alternate plans and provisions for Critical (II) characteristics and level (II) Critical nonconformances.

h. If a critical nonconformance is discovered during further processing or loading, the original manufacturer who introduced the critical nonconformance shall bear responsibility for the nonconformance.

i. The Government Quality Assurance Representative will perform the surveillance actions necessary to ensure compliance with this clause.

(End of clause)

(ES0500)